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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,455	02/01/2001	Willima S. Argraves	19113.0071U1	5273
23859	7590	03/24/2004	EXAMINER	
NEEDLE & ROSENBERG, P.C.			WEGERT, SANDRA L	
SUITE 1000			ART UNIT	
999 PEACHTREE STREET			PAPER NUMBER	
ATLANTA, GA 30309-3915			1647	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,455

Applicant(s)

ARGRAVES ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed 13 February 2004 has been entered. Claims 1-29 were withdrawn by the examiner (10 June 2003). Claims 30 and 33 have been amended. Claims 30-34 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections and/or Rejections

Continuity

The objection to the specification for not complying with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e), as set forth at p. 3 of the previous Office Action (10 June 2003), is *withdrawn* in view of the amendment adding continuity data to the first paragraph of the Specification (13 February 2004).

Abstract

The objection to the specification because it did not contain an Abstract, as set forth at page 3 of the previous Office Action (10 June 2003) is *withdrawn* in view of the amendment which added an Abstract (13 February 2004).

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Claim Objections

The objection to Claims 30 and 33 because they depended from non-elected claims, as set forth at page 3 of the previous Office Action (10 June 2003), is *withdrawn* in view of the amendment which made Claims 30 and 33 independent (13 February 2004).

Claim Rejections - 35 USC § 112, second paragraph-indefiniteness.

The rejection of Claims 30-34 for reciting or encompassing indefinite language ("holoparticle"), as set forth at page 4 of the previous Office Action (10 June 2003), is *withdrawn* in view of the amendment and arguments which clarified the precise definition and demonstrated widespread use of the term among those in the art (13 February 2004).

The rejection of Claims 33 and 34 for insufficient antecedent basis for use of the term "the polypeptide" is *withdrawn* in view of the amendment which substituted "a polypeptide" into the claims (13 February 2004). This rejection was set forth at page 4 of the previous Office Action (10 June 2003).

The rejection of Claims 30-34 for reciting or encompassing molecular weights, without specifying the method by which the molecular weights were obtained, is *withdrawn* in view of the amendment which added purification methods to independent claims (13 February 2004). This rejection was set forth at page 4 of the previous Office Action (10 June 2003).

Claim Rejections - 35 USC § 102

The rejection of Claims 30-34 as being unpatentable over Mcknight, et al (1992, JBC, 267: 12131-12141) and Matsumoto, et al (1997, JBC, 272: 16778-16782), is *withdrawn* in view

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of the amendment which added continuity data to the first paragraph of the Specification, and for the detailed explanation of what comprises a *holoparticle*, thus distinguishing the methods used from the prior art (13 February 2004). This rejection was set forth at pages 4-5 of the previous Office Action (10 June 2003).

New Objections and/or Rejections

Claim Rejections - 35 USC § 112, second paragraph-indefiniteness.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Currently amended Claim 30 recites the term "*the* functional HDL receptor." There is insufficient antecedent basis for use of this phrase, in the singular, in light of the receptor being used in an indefinite way as to number ("*an* isolated mammalian receptor") in the preamble of the claim.

35 USC § 112, first paragraph – Written Description.

Claims 30-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 30-34 are directed to methods of using a functional HDL receptor to assay for compounds that can modulate HDL holoparticle binding. Dependent claims recite use of the receptor for measuring production of mRNA, changes in receptor density or receptor-complex internalization.

The specification teaches use of a cubulin receptor (Specification, pages 2-7, for example) to study HDL holoparticle uptake (also see: Hammad, et al, 1999, PNAS, 96: 10158-10163). However, the claims encompass any related receptor that binds HDL holoparticle. This may be a large genus of receptors; Kollect, et al, for example discusses use of three such receptors for similar assays (Kollect, et al, 2002, Am. J. Respir. Cell Mol. Biol., 27: 57-63). The specification does not teach functional or structural characteristics of all encompassed polypeptides used for the claimed methods. The description of use of one HDL holoparticle receptor is not adequate written description of an entire genus of functionally equivalent polypeptides.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116).

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With the exception of the cubulin receptor referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed receptor polypeptides, and therefore, would not know how to use them. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of use. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only use of a cubulin receptor, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A

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shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

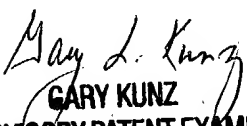
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW

3/17/04


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